

REMARKS

Claims 1-6 and 8-13 are pending. Claims 8-13 have been withdrawn. Claim 1 is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 (Sunshine et al.) and U.S. Patent No. 4,943,565 (US '565 Tencza et al.). Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Canadian Patent No. 1,336,687 (CA '687 Tencza et al.). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Initially, it should be noted that Claim 7 was cancelled in the amendment filed on July 30, 2008. As such, the rejections of Claim 7 are moot.

Claim 1 is directed to a solid pharmaceutical dosage form comprising caffeine, a disintegrant selected from the group consisting of sodium starch glycolate, crosslinked carboxymethylcellulose, and mixtures thereof, and a cephalagic, wherein the caffeine is in the form of uncoated particles having an average particle size of about 70 to 600 microns, and wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Sunshine et al., discussed previously in Applicants' Amendment filed July 30, 2008, does not disclose a composition comprising caffeine, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Accordingly, Claim 1 is patentable over Sunshine et al.

US '565 Tencza et al., also discussed previously in Applicants' Amendment filed July 30, 2008, discloses a sample, CW-3446-54B, where 80% of the caffeine is dissolved in 5

minutes. Notably, sample CW-3446-54B is formulated with 5 mg of Polyplasdone XL-10 (see col. 7, lines 30-33), which is a non-ionic, crosslinked PVP Crospovidone. In contrast, Claim 1 of the present application requires the inclusion of a disintegrant selected from the group consisting of sodium starch glycolate, crosslinked carboxymethylcellulose, and mixtures thereof. (See Amendment dated July 30, 2008). Thus, sample CW-3446-54B does not meet the compositional requirements of Claim 1. Moreover, Applicants note that the dissolution rate of 80% caffeine in 5 minutes exhibited by sample CW-3446-54B is significantly below the requirement stated in Claim 1, where at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm. Clearly, 80% is NOT the same as at least 95%. As such, sample CW-3446-54B would not meet the requirements of Claim 1. In addition, US '565 Tencza et al. discloses a sample CW 3446-58 that exhibits 75% dissolution of caffeine in 4 minutes. Here again, sample CW 3446-58 falls short of the requirement that at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as recited in Claim 1. As such, Claim 1 is patentable over US '565 Tencza et al.

Therefore, it is apparent that US '565 Tencza et al. does not remedy the deficiencies of Sunshine et al. That is, neither Sunshine et al. nor US '565 Tencza et al. disclose or teach a solid pharmaceutical dosage form comprising caffeine and a disintegrant selected from the group consisting of sodium starch glycolate, crosslinked carboxymethylcellulose, and mixtures thereof, wherein at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Therefore, Claim 1 is patentable over Sunshine et al. and US '565 Tencza et al. whether considered separately or in combination.

CA '687 Tencza et al. was discussed previously in Applicants' responses filed August 13, 2007 and February 4, 2008. CA '687 Tencza et al. discloses a sample CW-3708-29B, where the dissolution rate of caffeine in the sample is 85% of the caffeine is dissolved after 5.7 minutes (+/- 0.9). Here again, the composition of sample CW-3708-29B does not meet the requirements set forth in Claim 1. First of all, sample CW-3708-29B utilizes Crosspovidone XL-10 and Povidone as the disintegrants. As noted previously, Claim 1 of the present invention requires a disintegrant selected from the group consisting of sodium starch glycolate, crosslinked carboxymethylcellulose, and mixtures thereof. As such, sample CW-3708-29B does not meet the requirements of Claim 1. Moreover, the dissolution rate of sample CW-3708-29B is lower than the dissolution rate of the dosage form recited in Claim 1, where at least 95 % of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm. Clearly, 85% dissolution in 5.7 minutes is NOT the same as at least 95% dissolution. As such, Claim 1 is patentable over CA '687 Tencza et al.

The Examiner contends that it would have been obvious that at least 95% of the caffeine in the caffeine composition tablet of TENCZA et al. would dissolved within 5 minutes since the reference teaches that at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes.

Applicants respectfully disagree. At least 75% dissolution in under 45 minutes is NOT the same as at least 95% dissolution in 5 minutes. If the Examiner thinks otherwise, then Applicants respectfully request that the Examiner provide his rationale. Otherwise, Applicants maintain that the data provided by in CA '687 Tencza et al. demonstrates otherwise (see discussion above). As such, CA '687 Tencza et al. does not disclose a solid pharmaceutical dosage form comprising caffeine, wherein at least 95 % of the caffeine dissolves within 5

minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm. Accordingly, Claim 1 is patentable over CA '687 Tencza et al.

Claims 2-6 directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 are patentable over Sunshine et al., US '565 Tencza et al. and CA '687 Tencza et al., taken separately or in combination.

In view of the foregoing remarks, Applicant respectfully requests favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

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